K003392

SHL
TeleMedicine
International Ltd.

JAN 25 2001

510(k) Summary of Safety and Effectiveness

Submitter Information: SHL Telemedicine International Ltd.
90 Yigal Alon St.
Tel Aviv, 67891
Israel
tel: 972-3-5612212
fax: 972-3-6242414

Proprietary Name and Model: Cardio Monitor Center Vision Software

Common/Usual Name: ECG Display and Storage Software

Classification Name: Electrocardiograph (21 CFR 870.2340)

Predicate Device: The predicate device is the SHL Cardio Vision Software (K981807)

Device Description:
The Cardio Monitor Center Vision software is a program which runs on a personal computer and is used for the display and storage of Electrocardiogram recordings. The software receives an input signal containing the ECG data from an ECG receiving center. The receiving center is either connected to the computer on which the Cardio Monitor Center Vision software is running via a serial port or it is a card that resides within the computer. The ECG receiving center receives the ECG signal from an ECG recording device either via direct connection or via telephone. The software interprets the digital signal and displays it on the screen in real time as a single or multiple lead ECG plot.

The received ECG signal can be stored on the disk and can be compared to previous ECG recordings for that patient. In addition, measurements can be performed on the ECG plot.

Intended Use:
The Cardio Monitor Center Vision software is intended for use by trained medical staff for visualization and measurement of ECG recordings to be used in the monitoring of a patient's cardiac condition together with knowledge of the patient's general condition and other medical data on record.

Comparison to Predicate Device:
The Cardio Monitor Center Vision Software is a new version of the Cardio Vision Software, and it has the same intended use, basic functionality, and target population. The Cardio Monitor Center Vision Software provides a

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number of new features including support for a more advanced ECG receiving center, more advanced algorithms for automatic lead detection on 12 lead transmissions, calculation of augmented unipolar leads from simultaneously recorded bipolar leads, and more convenient ECG editing and display tools.

Safety:
The risk of all identified potential safety hazards is reduced by software design and testing and by the use of the device only by trained medical staff.

Bench Data:
Artificial square and triangle wave signals were fed into the receiving center, and the resulting ECG data was displayed and written to a log file. Comparison of the log file and the display with the original signal verified that the data sampling, data processing, and display modules function properly.

Clinical Data:
The comparison of Cardio Vision Software printouts with simultaneous ECG strip chart output demonstrated that the Cardio Vision Software processes and presents ECG data consistently and accurately.

Substantial Equivalence:
The safety and effectiveness of the Cardio Monitor Center Vision software are similar to that of its predicate device. It is SHL's opinion that the Cardio Monitor Center Vision software is substantially equivalent to its legally marketed predicate device in terms of safety and effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 25 2001

Mr. Iki Alroy
SHL Telemedicine International Ltd.
90 Yigal Alon Street
Tel Aviv
Israel

Re: K003392
Trade Name: Cardio Monitor Center Vision; Model S-CV7-00
Regulatory Class: II (two)
Product Code: DPS
Dated: October 31, 2000
Received: October 31, 2000

Dear Mr. Alroy:

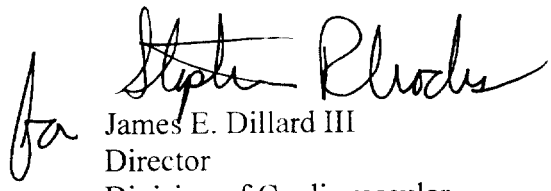
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K003392

510(k) Number (if known):

Device Name: CARDIO MONITOR CENTER VISION

Indications For Use:

VISUALIZATION AND MEASUREMENT OF ECG RECORDINGS TO BE USED BY TRAINED MEDICAL STAFF IN THE MONITORING OF CARDIAC CONDITION

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003392

31 OCT 00 15 59

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

CV
II